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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DUTT, ADITI	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,518	STEFFAN ET AL.	
	Examiner	Art Unit	
	Aditi Dutt	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 14-18, 27-32, 43, 47, 51, 55, 59 and 63, drawn to a method of treating neurodegeneration in a patient by administering a therapeutically effective amount of SUMOylation blocker, classified in class 514, subclass 2, for example.

II. Claims 6-7, 19-20, 33-35, 44, 48, 52, 56, 60 and 64, drawn to a method of treating neurodegeneration in a patient by administering a therapeutically effective amount of deSUMOylation enhancer, classified in class 514, subclass 2, for example.

III. Claims 8-11, 21-24, 36-39, 45, 49, 53, 57, 61 and 65, drawn to a method of treating neurodegeneration in a patient by administering a therapeutically effective amount of Ubiquitination activator, classified in class 514, subclass 2, for example.

IV. Claims 12-13, 25-26, 40-42, 46, 50, 54, 58, 62 and 66, drawn to a method of treating neurodegeneration in a patient by administering a therapeutically effective amount of deUbiquitination inhibitor, classified in class 514, subclass 2, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-IV are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, inventions I-IV are directed to methods that are distinct, use different starting materials, follow different procedure and evaluation protocols, have distinct end-points and are not required one for the other. Invention I requires the administration of SUMOylation blocker to treat neurodegeneration in a patient, which is not required by the other groups. Invention II requires the administration of deSUMOylation enhancer to treat neurodegeneration in a patient, which is not required by the other groups. Invention III requires the administration of Ubiquitination activator to treat neurodegeneration in a patient, which is not required by the other groups. Invention IV requires the administration of deUbiquitination inhibitor to treat neurodegeneration in a patient, which is not required by the other groups. Therefore, a search of all the four methods in one patent

application would result in an undue search burden. The searches for the methods are not co-extensive, and the subject matter is divergent.

4. Because these inventions are independent or distinct for the reasons given above, and require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Species Elections

5. This application contains claims directed to the following patentably distinct species of the claimed inventions I-IV.

6. A) SUMOylation blocker:

a) Inhibitor E1 SUMO activating enzyme

b) Inhibitor E2 SUMO conjugating enzyme

c) Inhibitor E3 SUMO ligating enzyme

If applicant elects Invention I, one species of SUMOylation blocker must also be selected to be considered responsive.

7. Each of the above SUMOylation blockers will determine characteristically different peptide sequences that have different mechanism of actions from one another and, therefore, represent a

patentably distinct invention and would require a separate search of the art that would be burdensome to the examiner.

8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 1, 14, 27, 32, 43, 47, 51, 55, 59 and 63 are generic.

9. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. B) Ubiquitination activator:

d) Activator of E1 Ubiquitin activating enzyme

e) Activator of E2 Ubiquitin conjugating enzyme

f) Activator of E3 Ubiquitin ligating enzyme

13. **It is noted that the Examiner has interpreted claims 10 and 38 to read upon E2 Ubiquitin conjugating enzyme.**

14. If applicant elects Invention III, one species of Ubiquitination activators must also be selected to be considered responsive.

15. Each of the above Ubiquitination activators will determine characteristically different peptide sequences that have different mechanism of actions from one another and, therefore, represent a patentably distinct invention and would require a separate search of the art that would be burdensome to the examiner.

16. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 8, 21, 36, 45, 49, 53, 57, 61 and 65 are generic.

17. Applicant is advised that a reply to this requirement must include an

identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

18. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

19. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

20. C) Neurodegenerative disease:

g) Huntington's Disease

h) Alzheimer's disease

i) Parkinson's disease

j) Amyotrophic lateral sclerosis

k) Kennedy's Disease

l) Spinocerebellar ataxia

m) Dentatorubral-pallidoluysian atrophy

n) Epilepsy

o) Diabetes Mellitus

p) Spongiform encephalopathy

q) Prion-related disease

r) Machado-Joseph's disease

s) Schizophrenia

21. If applicant elects Inventions I, II, III or IV one species of neurodegenerative disease must also be selected to be considered responsive.

22. Each of the above neurodegenerative diseases will determine characteristically different etiology, treatment options and levels of success from one another and, therefore, will represent a patentably distinct invention and would require a separate search of the art that would be burdensome to the examiner.

23. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall

be restricted if no generic claim is finally held to be allowable. Currently claims 1-42 and 59-62 are generic.

24. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

25. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

26. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

27. In response to this requirement, applicants must elect from Groups I-IV, and must additionally elect a species of SUMOylation blocker, Ubiquitination activator and neurodegenerative disease for consideration. Applicant is advised that in order for the reply to this requirement to complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

28. Applicant is reminded that upon the cancellation of claims to a nonelected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the required under 37 C.F.R. 1.17(l).

Advisory Information

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is 571-272-9037. The examiner can normally be reached on M-F 9.00 a.m. to 5.00 p.m. (Eastern standard time).
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD
20 July 2006

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER